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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/991,933

11/26/2001

Beth E. Drees

ECH-001

8812

7590

06/07/2005

M.WAYNE WESTERN
THORPE NORTH & WESTERN
PO BOX 1219
SANDY, UT 84091-1219

EXAMINER

COUNTS, GARY W.

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,933

Applicant(s)

DREES ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-58 and 60-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-58 and 60-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

PD

DETAILED ACTION

The Request for Continued Examination and the amendment filed April 6, 2005 is acknowledged and has been entered.

Claim Objections

1. Claim 60 is objected to because of the following informalities: Claim 60, line 2 the recitation "mount" should be --amount--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 49-58 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A step of contacting a test solution with a substrate phosphoinositide lipid and the enzyme to produce the target lipid critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). On page 17-18 of the specification steps of contacting a substrate and an enzyme are included in the method. However, the invention as recited cannot work because if substrate and the enzyme are not included in the assay, the phosphoinositide kinase activity cannot be quantitated as required in the claim. Therefore, the method must also include a step of contacting a substrate phosphoinositide lipid and the enzyme to produce the target lipid.

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3. Claims 60-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 5, lines 10-23 in the specification. The applicant discloses "the present invention is further directed to a lipid assay kit, which includes a target lipid, a competing lipid, and a protein that has a lipid recognition motif that interacts with the target lipid and the competing lipid. The target lipid has a stronger affinity to the lipid recognition motif than the competing lipid. The assay kit can further include a multi-well assay plate. The multi-well assay plate preferably includes the competing lipid immobilized in wells of the multi-well assay plate. The lipid assay kit can further include primary and secondary antibodies. As mentioned with respect to the assay method, additional competing and noncompeting lipids can also be present in the solution, enabling the assay method of the present invention to be used with complex solutions including bodily tissues, fluids, and plasma." The applicant does not disclose the kit comprises instructions for using the assay kit. There is no description in the specification disclosing that the kit comprises instructions for using the assay kit.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 49-58 and 60-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim requires the quantification of phosphoinositide kinase activity. However the body of the claim does not recite the presence or activity of the enzyme or the substrate. The claim merely requires an already made product (target lipid). There is no clear indication of the presence of enzyme and thus is not commensurate with the preamble of the claim.

Claim 49 the recitation "which is" is vague and indefinite. The recitation is not a positive limitation that the target lipid is in the presence of or acted upon by the enzyme or substrate. Please clarify.

Claim 49 the recitation "measuring decreases of said non-radioactive signal of said competing phosphoinositide lipid which correlates positively with said phosphoinositide kinase activity" is vague and indefinite because it is unclear how this correlates with the preamble of the claim. It is recommended to change to --measuring a signal wherein a decrease in signal correlated with an increase in target lipid is directly correlated with the activity of the phosphoinositide kinase activity--.

Claim 60 is vague and indefinite because of the recitation "according to the method of claim 1". Claim 1 which is recited has been cancelled by applicant and therefore it is unclear what applicant is referring to.

Claim 60 is vague and indefinite because it is unclear if applicant intends to claim the phosphoinositide kinase and substrate phosphoinositide lipid which are essential to the method of claim 49 because the recitation "which is a phosphorylation product of the reaction between the phosphoinositide kinase and a substrate

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phosphoinositide lipid' does not require that the phosphoinositide kinase and substrate phosphoinositide lipid. The recitation is not a positive limitation that the target lipid is in the presence of or acted upon by the enzyme or substrate. Therefore, it is recommended that applicant positively recite the reagents of the kit which are used in the methods of quantification of phosphoinositide kinase activity.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gary Counts


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/03/05